Aventis Pharmaceuticals

Aventis

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9 June, 2000

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane Rm 1061
Rockville, MD 20852

Docket 98-D-0969
Risk Assessment of the Public Health Impact of Streptogramin Resistance in Enterococcus faecium Attributable to the Use of Streptogramins in Animals

Dear Sir or Madame,

On behalf of Aventis Pharmaceuticals, I would like to acknowledge your efforts regarding the development of a risk assessment model to evaluate the transfer of resistance determinants from bacteria in food-producing animals to bacteria in humans, specifically, as it will be applied to assess the association between the development of streptogramin (i.e. quinupristin-dalfopristin) resistant *Enterococcus faecium* in humans and the use of virginiamycin in food-producing animals.

Aventis is open to assisting you in your efforts surrounding this investigation, although there is no definitive Aventis corporate policy position on this issue today.

Please contact me (610-454-5471) or Ms. Mary Elicone (610-454-5859) if you wish to discuss.

Sincerely yours,

John J. Savarese, MD, PhD
Senior Director, Regulatory Affairs

cc: Gary Chikami, M.D., Director
RE: Synercid NDA's 50-747 and 50-748
Division of Anti-Infective Drug Products (HFD-520)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
3rd Floor, Room N303
Rockville, MD 20850

98D-0969

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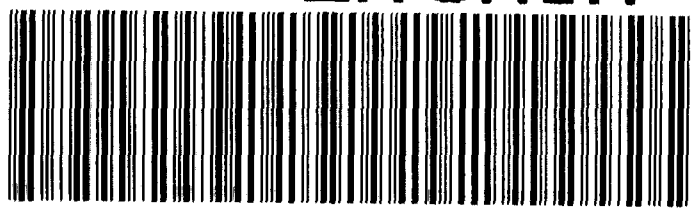

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